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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

VAC.483

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/937942

INTERNATIONAL APPLICATION NO.
PCT/US00/08821INTERNATIONAL FILING DATE
31 March 2000PRIORITY DATE CLAIMED
02 April 1999

TITLE OF INVENTION

VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT

APPLICANT(S) FOR DO/EO/US

JOHNSON, Royce W.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☒ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

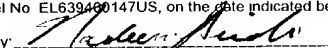
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Date

10/2/01

By


 Nadeem Bredi (Person Mailing)

T0200T"2462E660

413 Rec'd PCT/PTO 02 OCT 2001

U.S. APPLICATION NO. 097/937942

INTERNATIONAL APPLICATION NO
PCT/US00/08821ATTORNEY'S DOCKET NUMBER
VAC.48321. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO. \$1000.00International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$860.00International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00**ENTER APPROPRIATE BASIC FEE AMOUNT =****CALCULATIONS PTO USE ONLY**

\$ 100.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	10 - 20 =	0	x \$18.00	\$ 0.00
Independent claims	1 - 3 =	0	x \$80.00	\$ 0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$ 0.00

TOTAL OF ABOVE CALCULATIONS =

\$ 100.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2.

\$

SUBTOTAL =

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Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$ 0.00

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Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
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\$ 0.00

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\$ 200.00

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refunded:**

\$

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- b. ☒ Please charge my Deposit Account No. 50-0326 in the amount of \$ 200.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
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information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

KINETIC CONCEPTS, INC.

Attn: Nadeem G. Bridi

P.O. Box 659508

San Antonio, Texas 78265-9508

USA

SIGNATURE

Nadeem G. Bridi

NAME

42,361

REGISTRATION NUMBER

VACUUM ASSISTED CLOSURE SYSTEM
WITH PROVISION FOR INTRODUCTION OF AGENT

RELATED APPLICATION:

5 This application claims priority to United States provisional patent application Serial No. 60/127,595 entitled VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT filed April 2, 1999. By this reference, the full disclosure, including the drawings, of U.S. provisional patent application Serial No. 60/127,595 is incorporated herein.

10 TECHNICAL FIELD:

The present invention relates to the healing of wounds. More specifically, the present invention relates to the vacuum assisted closure (VAC) of wounds wherein a growth factor or other agent is introduced to a wound site through grafting with a VAC pad in order to facilitate wound healing.

BACKGROUND ART:

Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can

eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative pressure, commonly referred to as vacuum assisted closure (VAC) therapy, typically involves mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, VAC therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While VAC therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the inflammatory process is very unique to the individual patient, even the addition of VAC therapy does not result in a fast enough response, especially during the occlusion and initial cleanup and rebuilding stages, for adequate healing of some wounds. It is therefore a principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through the introduction of growth factors and/or other agents that facilitate wound healing.

DISCLOSURE OF THE INVENTION:

In accordance with the foregoing objects, the present invention – a method and apparatus for the introduction to a wound undergoing vacuum assisted closure (VAC) therapy of a wound healing agent – generally comprises a foam pad for insertion substantially into a wound site and a wound drape for sealing enclosure of the foam pad at the wound site. According to the invention, the foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage. Additionally, the foam pad is predisposed, through

grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbials or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

According to the preferred method of the present invention, a growth factor or other wound healing agent is added to the previously known VAC therapy through modification as necessary of the VAC system's foam pad. Such growth factors as the basic fibroblast growth factor (bFGF) are known to accelerate wound healing due to their potent angiogenesis and granulation tissue formation activities. As has been demonstrated even with difficult to heal wounds, such as infected wounds, burn wounds and diabetic wounds, the resultant activities lead to the rapid reepithelialization and contraction of the wound. The combination of VAC therapy with growth factor introduction, through the modification of the foam pad and predisposition thereof with the bFGF, is therefore thought to be an important contribution to the wound healing arts.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions, the following drawing and exemplary detailed description and the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiment follows together with an illustrative figure, wherein like reference numerals refer to like components, and wherein:

The figure shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site.

BEST MODE FOR CARRYING OUT THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – a vacuum assisted closure system with provision for introduction of agent, the scope of which is limited only by the claims appended hereto.

Referring now to the figure, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. According to the invention, the

foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage. Additionally, the foam pad 11 is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbials or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and the drawings, is incorporated herein as though now set forth in its entirety. Additionally, such a VAC system is readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies.

As detailed in the '901 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction, but in this application may comprise a conventional sponge cellulose type dressing as necessary for introduction of the desired agent. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 14, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. Finally, the '901 application also details the wound drape 13, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the exception that the foam pad 11 of the present invention is modified as necessary for the introduction of a growth factor. Such growth factors as the basic fibroblast growth factor (bFGF) are known to accelerate wound healing due to their potent angiogenesis and granulation tissue formation activities. As has been demonstrated even with difficult to heal wounds, such as infected wounds, burn wounds and diabetic wounds, the resultant activities lead to the rapid reepithelialization and contraction of the wound. The combination of VAC therapy with growth factor introduction, through the modification of the foam pad 11 and predisposition thereof with the bFGF, is therefore thought to be an important contribution to the wound healing arts. Likewise, the present method presents an excellent opportunity for

the introduction to the wound site 12 of anti-microbial agents, whether alone or in combination with bFGF or other agents.

While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that while the preferred embodiment of the present invention comprises grafting the desired agent onto the foam pad 11 of the VAC system, those of ordinary skill in the art, with the benefit of this exemplary disclosure, will readily recognize many substantially equivalent modes for introduction of the desired agent. For example, in the case of a foam pad 11 that has not been predisposed with an agent or that has been predisposed with an agent which, over time, has subsequently been exhausted into the wound site 12, the desired agent may be injected with a needle and syringe, or the like, through the wound drape 13 and into the foam pad 11. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

INDUSTRIAL APPLICABILITY:

The present invention is applicable to the wound healing arts.

CLAIMS:

What is claimed is:

1. A therapeutic combination for promoting wound healing in mammals, said
5 therapeutic combination comprising:
a porous pad which is permeable to fluids and adapted for positioning within a
sealable space defined in part by a wound surface;
a tube having a first end in fluid communication with said porous pad and a second
end in fluid communication with a vacuum source, said vacuum source being adapted to
10 apply negative pressure to said porous pad through said tube; and
said porous pad being predisposed with a wound healing factor.
2. The therapeutic combination as recited in claim 1, wherein said wound healing factor
comprises basic fibroblast growth factor.
- 15 3. The therapeutic combination as recited in claim 2, wherein said basic fibroblast
growth factor is grafted to said porous pad.
4. The therapeutic combination as recited in claim 1, wherein said wound healing factor
20 comprises an anti-microbial agent.
5. The therapeutic combination as recited in claim 4, wherein said anti-microbial agent
comprises an antibiotic.
- 25 6. The therapeutic combination as recited in any of the preceding claims, wherein said
porous pad is predisposed with a plurality of wound healing factors.
7. The therapeutic combination as recited in any of the preceding claims, said
therapeutic combination further comprising a wound drape for sealing said porous pad within
30 said sealable space.
8. The therapeutic combination as recited in claim 7, wherein a quantity of a wound
healing factor is introduced to said porous pad by injection through said wound drape.

9. The therapeutic combination as recited in claim 8, wherein said quantity of wound healing factor is in addition to said wound healing factor predisposed upon said porous pad.

10. The therapeutic combination as recited in claim 9, wherein said quantity of wound
5 healing factor comprises the same type of factor as said wound healing factor predisposed upon said porous pad.

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International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US00/08821

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(30) Priority Data:
60/127,595 2 April 1999 (02.04.99) US

(71) Applicant (for all designated States except US): KINETIC CONCEPTS, INC. [US/US]; 8023 Vantage Drive, San Antonio, TX 78230 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): JOHNSON, Royce, W. [US/US]; 114 Rimdale, Universal City, TX 78148 (US).

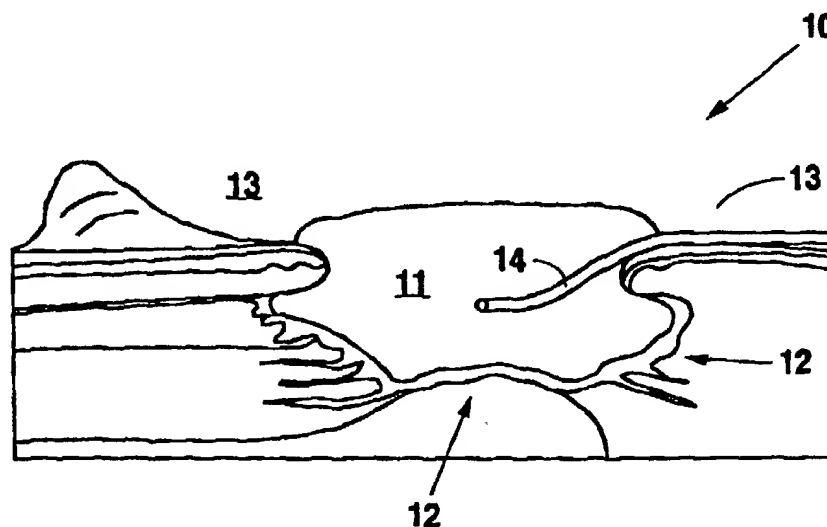
(74) Agents: COLTON, Wayne, J.; Wayne J. Colton, Inc., The Milam Building, Suite 1108, 115 East Travis Street, San Antonio, TX 78205 (US) et al.

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT



(57) Abstract

A method, and apparatus for the introduction to a wound under vacuum assisted closure (VAC) therapy of a wound healing agent, generally comprises a foam pad (11) for insertion substantially into a wound site (12), and a wound drape (13) for sealing enclosure of the foam pad at the wound site. The foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage. Additionally, the foam pad is predisposed, through grafting or other techniques known to those of ordinary skill in the art, with basic fibroblast growth factor (bFGF), anti-microbial or other factors, also known to those of ordinary skill in the art, for the promotion of increased wound healing.

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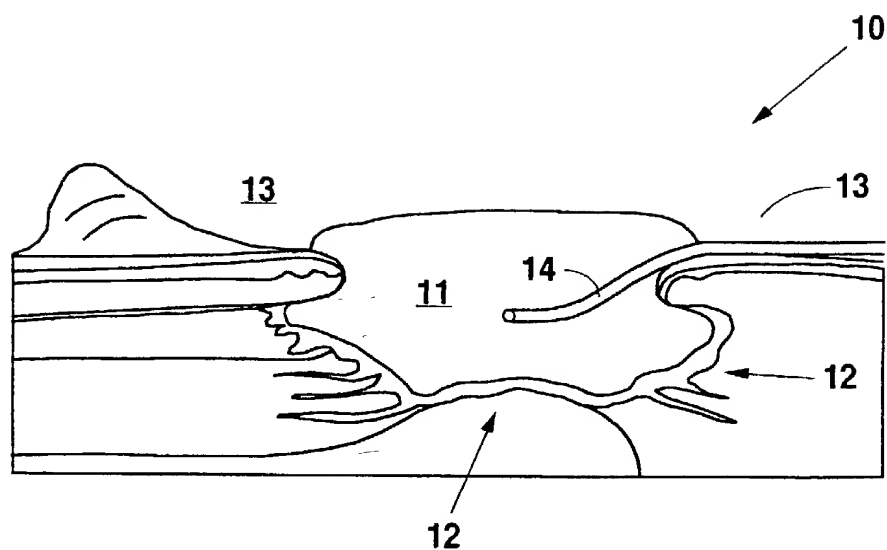


Fig. 1

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	Attorney Docket Number VAC.483		
	First Named Inventor JOHNSON, Royce		
	COMPLETE IF KNOWN		
	Application Number /		
Filing Date			
Group Art Unit			
Examiner Name			

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled.

VACUUM ASSISTED CLOSURE SYSTEM WITH PROVISION FOR INTRODUCTION OF AGENT

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY)

31 March 2000

as United States Application Number or PCT International

Application Number PCT/US00/08821 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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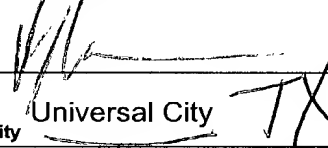
☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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City Universal City		State TX		ZIP 78265-9508	
Country US		Telephone 210-255-4543		Fax 210-255-4440	
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NAME OF SOLE OR FIRST INVENTOR :				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Royce W.		Family Name or Surname Johnson			
Inventor's Signature 				Date 25 SEP 01	
Residence: City Universal City TX		State TX		Country US	
Citizenship US					
Mailing Address 114 Rimdale					
City Universal City		State TX		ZIP 78148	
Country US					
NAME OF SECOND INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Family Name or Surname			
Inventor's Signature				Date	
Residence: City		State		Country	
Citizenship					
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City		State		ZIP	
Country					
<input type="checkbox"/> Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto					